Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Directive	2001/0253(COD)
Medicinal products for human use: Community code Amending Directive 2001/83/EC 1999/0134(COD) Subject 4.20.04 Pharmaceutical products and industry	Procedure completed

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health, Consumer Policy	PPE-DE GROSSETÊTE Françoise	13/09/2001
Former committee responsible		
ENVI Environment, Public Health, Consumer Policy	PPE-DE GROSSETÊTE Françoise	13/09/2001
Former committee for opinion		
BUDG Budgets	PSE KUCKELKORN Wilfried	22/01/2002
CONT Budgetary Control	ELDR MULDER Jan	21/02/2002
JURI Legal Affairs and Internal Market	The committee decided not to give an opinion.	
ITRE Industry, External Trade, Research, Energy	PSE READ Imelda Mary	23/01/2002
AGRI Agriculture and Rural Development	PPE-DE STURDY Robert	08/01/2002

Council of the European Union

Council configuration	Meeting	Date
Competitiveness (Internal Market, Industry, Research and Space)	2570	11/03/2004
Agriculture and Fisheries	2528	29/09/2003
Employment, Social Policy, Health and Consumer Affairs	2512	02/06/2003
Employment, Social Policy, Health and Consumer Affairs	2470	02/12/2002
Health	2440	26/06/2002

European Commission

Commission DG	Commissioner
Internal Market, Industry, Entrepreneurship and SMEs	

Key events

13/12/2001	Committee referral announced in Parliament, 1st reading		

26/06/2002	Debate in Council	2440	Summary
02/10/2002	Vote in committee, 1st reading		Summary
02/10/2002	Committee report tabled for plenary, 1st reading	A5-0340/2002	
22/10/2002	Debate in Parliament		
23/10/2002	Decision by Parliament, 1st reading	T5-0505/2002	Summary
02/12/2002	Debate in Council	2470	Summary
09/10/2003	Committee referral announced in Parliament, 2nd reading		
27/11/2003	Vote in committee, 2nd reading		Summary
16/12/2003	Debate in Parliament		
17/12/2003	Decision by Parliament, 2nd reading	T5-0577/2003	Summary
11/03/2004	Act approved by Council, 2nd reading		
31/03/2004	Final act signed		
31/03/2004	End of procedure in Parliament		
30/04/2004	Final act published in Official Journal		

Technical information

Procedure reference	2001/0253(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Directive
	Amending Directive 2001/83/EC 1999/0134(COD)
Legal basis	EC Treaty (after Amsterdam) EC 095; EC Treaty (after Amsterdam) EC 152
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/5/16947

Documentation gateway

Legislative proposal		COM(2001)0404	26/11/2001	EC	Summary
Committee draft report		PE290.143	21/05/2002	EP	
Committee opinion	AGRI	PE307.225/DEF	19/06/2002	EP	
Committee opinion	ITRE	PE316.248/DEF	20/06/2002	EP	
Committee opinion	CONT	PE305.679/DEF	21/06/2002	EP	
Committee opinion	BUDG	PE318.692/DEF	03/07/2002	EP	
Amendments tabled in committee		PE290.143/AM	29/08/2002	EP	
Economic and Social Committee: opinion, report		CES1007/2002	18/09/2002	ESC	

Amendments tabled in committee		PE290.143/AMC	25/09/2002	EP	
Committee report tabled for plenary, 1st reading/single reading		A5-0340/2002	02/10/2002	EP	
Text adopted by Parliament, 1st reading/single reading		T5-0505/2002 OJ C 300 11.12.2003, p. 0166-0352 E	23/10/2002	EP	Summary
Modified legislative proposal		COM(2003)0163	03/04/2003	EC	Summary
Council statement on its position		12155/1/2003	24/09/2003	CSL	
Council position		10950/3/2003 OJ C 297 09.12.2003, p. 0041-0071 E	29/09/2003	CSL	Summary
Commission communication on Council's position		SEC(2003)1082	07/10/2003	EC	Summary
Committee draft report		PE337.033	17/10/2003	EP	
Amendments tabled in committee		PE337.033/AM	20/11/2003	EP	
Amendments tabled in committee		PE337.033/ANC	21/11/2003	EP	
Committee recommendation tabled for plenary, 2nd reading		A5-0446/2003	27/11/2003	EP	
Text adopted by Parliament, 2nd reading		T5-0577/2003 OJ C 091 15.04.2004, p. 0133-0298 E	17/12/2003	EP	Summary
Commission opinion on Parliament's position at 2nd reading		COM(2004)0124	17/02/2004	EC	Summary

Additional information

European Commission	EUR-Lex

Final act

Directive 2004/27
OJ L 136 30.04.2004, p. 0034-0057 Summary

Medicinal products for human use: Community code

PURPOSE : to amend Directive 2001/83/EC on the community code relating to medicinal products for human use. CONTENT : In general terms the pharmaceutical legislation needs to be revised (see COD010252), in view of lessons learnt as well as scientific and technical progress. The main amendments are as follows: -the definition of medicinal product is adapted to take account of new therapies and their particular mode of administration. -since the possible duality of certain "borderline" products (medical devices, cosmetics, biocides etc.) has led to differences of opinion as to the applicable legislation, it is proposed that when a product fully meets the definition of a medicinal product, but may also meet the definition of other regulated products, the pharmaceutical legislation should apply. -adaptations are proposed to certain provisions relating to the marketing authorisation application file. -in the case of abridged marketing authorisation procedures, the concept of "essentially similar" medicinal products is abandoned since it actually refers to generic medicinal products, a definition of which is inserted, together with a definition of reference medicinal product. -the administrative protection period for data on the reference medicinal product is harmonised at ten years. -any medicinal product not compulsorily subject to the centralised procedure will be covered by the decentralised or mutual recognition procedure, on condition that it is intended for the market of more than one Member State. These procedures are thus still optional for other medicinal products which represent a therapeutic innovation and will be the procedure of choice for generic medicinal products. -the mutual recognition procedure has been criticised because of difficulties encountered in practice. Added to the general principles of mutual recognition is a new decentralised procedure for medicinal products not yet authorised in the Community, where Member States would cooperate before a decision is taken by one of them. -the establishment of the co-ordination group to whom disagreements are referred under the new decentralised procedures. -the obligation to renew marketing authorisation every five years is removed. (see COD010252) -the referral procedure is amended, and the overall length is reduced from 90 days to 60 days. -Commission decision-making is to be subject to a consultation procedure and a management procedure, depending on the case. -on inspection and surveillance matters, it is proposed that the regulation be extended to cover active substances used as starting materials in the manufacture of medicinal products. Provision is made for issuing certificates of good manufacturing practice attesting compliance with the relevant requirements. -there are provisions to ensure a

greater emphasis on a preventive approach with regard to pharmacovigilance. -the proposal introduces a limited mutual recognition procedure for homeopathy. Invented names may be used. The blanket prohibition on advertising is removed. ?

Medicinal products for human use: Community code

The Council held a policy debate on the basis of a Presidency questionnaire on three proposals - a Regulation (see COD/2001/0252) and two Directives (this text) and (COD/2001/0254) - the main aims of which are to achieve completion of the single market in the medicinal products sector, to improve the competitiveness of the pharmaceutical industry (particularly small and medium-sized enterprises) and to simplify Community legislation. The Opinion of the European Parliament at first reading should be available in October 2002. Two topics were discussed at this stage following the proceedings of the Working Party: - the scope of the proposal for a Regulation: the text provides for extension of the compulsory centralised Community procedure to medicinal products for human or veterinary use containing new active substances; a majority of delegations wanted to be able to continue to choose between a centralised system and a system of national authorisations with the principle of mutual recognition. Some delegations, however, made distinctions depending on whether the medicinal product was for human or veterinary use. Some delegations said they could support an extension of the scope for medicinal products for human use only. Delegations which recommended an optional system put forward the following main arguments: several delegations wanted the Commission to provide a better definition of medicinal products containing new active substances; several delegations expressed concern regarding the situation of small and medium-sized enterprises and argued that some flexibility was the best solution for them; some delegations expressed fears that extension of a centralised procedure would not take sufficient account of the views of national authorities. As regards medicinal products for veterinary use, some delegations pointed out that, since in some cases their use and authorisation involved only a few regional animal species (e.g. northern Finland), a national authorisation system would be preferable. Some delegations stressed in particular the need to improve the technical resources of the European Agency for the Evaluation of Medicinal Products (EMEA) - computerised files, national databases - and to extend its evaluation methods, along the lines of the methods available to the United States Food and Drug Administration. - the new composition of the Management Board of the European Agency for the Evaluation of Medicinal Products (EMEA): under the proposal this Board would consist of four representatives of the Member States, four representatives of the European Parliament, four representatives of the Commission and four representatives of patients and the industry; a very large majority of delegations wanted to maintain representation by Member States only. Two delegations stressed in particular the need for the Management Board to have a composition different from that of the European Food Safety Authority (EFSA) - a consultative body - taking account of the executive role of the EMEA in issuing authorisations for placing medicinal products on the market. The Council agreed to take account of these positions expressed by the Member States when continuing its discussions in the second half of 2002.?

Medicinal products for human use: Community code

The committee adopted the report by Françoise GROSSETÊTE (EPP-ED, F) tabling a large number of amendments to the proposal under the codecision procedure (1st reading). The main amendments were as follows: - the committee deleted the proposed derogation to the basic rules which would allow the pharmaceutical industry to provide information on medicines for AIDS, asthma and diabetes, on the grounds that this would be the first step toward consumer advertising of prescription medicines in the guise of 'disease education'. The industry was incapable of providing impartial information on its medicines and such information should therefore only come from independent sources; - it was proposed that the Commission should develop an information and education strategy to ensure that all patients could obtain objective, reliable and non-promotional information about medicines and other treatments; - the committee adopted a large number of amendments aimed at ensuring greater transparency and access to information for the public (including publicly-accessible registers and databases on medicinal products), as well as provisions on the legibility and clarity of packaging and patient information leaflets; - to speed up the time within which generic medicines can be brought onto the market, applicants should not be required to provide the results of pre-clinical tests or pre-clinical trials if they can demonstrate that the medicinal product is a generic of a reference medicinal product authorised for eight years in a Member State or in the Community, rather than ten years as proposed by the Commission. The committee added, however, that such a generic medicinal product cannot be manufactured or placed on the market until ten years have elapsed since the first authorisation of the reference product and that, in the case of a biogeneric medical product, pre-clinical tests and/or clinical trials shall be necessary; - generic drugs should be identified in all Member States with the same denomination of the internationally approved chemical name of the active substances and the name of the producer; - authorisation applications should include a confirmation that clinical trials for the medicinal product in question have not been carried out in developing countries unless that product is primarily geared to the domestic market in those countries; - in the first five years after being placed on the market, the package leaflet must bear the phrase 'Newly authorised medicinal product. Please notify any adverse reactions'; - Member States should be able to temporarily authorise the distribution of an unauthorised medicinal product in response to the suspected or confirmed spread of a pathogen which could cause harm.?

Medicinal products for human use: Community code

The European Parliament adopted, by 504 to 30 with 16 abstentions, the report by Mrs Françoise GROSSETETE (EPP-ED, F) which aims to update an EU code relating to pharmaceutical products, together with a number of amendments. The Parliament voted for a ban on direct advertising such products, thus rejecting the Commission's proposal for a pilot project to allow information to be provided on new drugs to treat diseases such as AIDS, asthma and diabetes. With regard to patent protection, MEPs voted for a period of 10 years, which could be extended to 11 in certain circumstances, with protection for the results of clinical tests during this period. MEPs take the view that this is a sufficient time period to guarantee the viability of new products before allowing generics on the market. Parliament proposes that Member States shall take all appropriate measures to ensure that the procedure for granting an authorisation to place a medicinal product on the market is completed within 150 days of a valid application, including 80 days for scientific data analysis and preparation of the report by the rapporteur. Parliament also wants to see the new rules applying to candidate countries. ?

Medicinal products for human use: Community code

The Council held an exchange of views, on the basis of a progress report from the Presidency, on some of the key issues raised by the proposal for a Regulation of the European Parliament and of the Council aimed at amending Community procedures for the authorisation and supervision of medicinal products for human and veterinary use. The Council requested the Permanent Representatives Committee to pursue work actively on the proposal, taking into account the positions expressed by delegations and the opinion of the European Parliament in first reading. In the light of this discussion, the President concluded that: - views continue to differ on the scope of the centralised authorisation procedure, with a slight majority opposed to its extension as regards medicinal products for Human use and a clear majority opposed as regards veterinary medicinal product; - a majority of delegations are favourable to each Member State being represented on the management board of the European Agency for the Evaluation of Medicinal Products; - a majority of delegations are in favour of maintaining a first renewal of market authorisations after five years, with unlimited validity thereafter.?

Medicinal products for human use: Community code

The Commission accepted 30 amendments proposed by the European Parliament. These include: - any authorisation, which is not followed within three years by the actual placing on the market of the authorised product, will cease to be valid; - the possibility of unannounced inspections by the competent authorities; - Member States may temporarily authorise the distribution of an unauthorised medicinal product in response to the suspected spread of a pathogen which could cause harm; - clarification that the data protection period of 11 years constitutes the maximum time; - the documents to be submitted by the applicant on the constituents of the medicinal product include the reference to its international non-proprietary name recognised by the WHO; - an applicant has to submit documents to prove that he will be able to meet certain pharmacovigilance obligations; - homeopathic products authorised before December 1993 do not need to be updated according to the new legislation; - the rules of procedure of the coordination group are to be made public; - the committee must specify the time limit for explanations by the applicant; - the Commission must prepare a draft decision in 15 and not 30 days; - the Rules of Procedure of the Standing Committee must be made public. The Commission accepted 48 amendments in part or in principle. These include: - the change in the period of validity foe the marketing authorisation. The latter for new medicinal products must initially be limited to five years' validity. After the first renewal, the marketing authorisation shall be considered to be valid indefinitely; - further clarification on the definition of a medicinal product. A reformulation is required to refer, in addition to pharmacological action, to immunological and metabolic action; - the deletion of certain parts of the definition of a homeopathic medicinal product. There is a rewording to reintroduce the reference to homeopathic stocks, which are an important step in the production of a homeopathic medicinal product; - the introduction of a definition of the risk/benefit balance; - the situation that a given product could fulfil the definition of different regulatory regimes. This excludes food, food supplements, medical devices and cosmetics from the scope of the Directive; reinforcement of the arbitration procedures. The option to refer to the Agency will be made into an obligation in the cases of referral where a Community interest is involved. A requirement for the marketing authorisation holder, and, within the limits of their responsibilities, the distributors, to provide suitable supplies; it is compulsory for Member States to take measures to require doctors and other healthcare professionals to report adverse reactions The Commission rejected 79 amendments proposed by the Parliament. These include: - the requirement for generic medicinal products authorised bythe Member States to be identified with the same denomination; - amendments which introduce the possibility of conducting the tests and trials needed for authorisation, submitting the application for authorisation, and authorising generic medicinal products during the ten year period of data protection; - amendments which require the competent authorities to set up a website containing information on the medicinal product and to include its address on the packaging; - including patients as a source of information adverse reactions that is forwarded directly to the holder of marketing authorisations; the proposal that a new category of medicinal product "herbal health product" be introduced.?

Medicinal products for human use: Community code

The Council's common position incorporates 20 amendments adopted by the European Parliament, which had been taken up unchanged in the Commission's amended proposal. In addition, the Council has accepted in part or in principle 42 amendments adopted by the European Parliament, which have been endorsed at least partially or in principle in the Commission's amended proposal. The Council has agreed on a number of changes, including editorial ones, to clarify the provisions of the text, to update terminology or to align the text with the proposal for a Regulation and the proposal for a Directive on medicinal products for veterinary use. The more substantial changes are described below: - deletion of the possibility to extend the data protection period to 11 years when a new therapeutic use is found for a new product; - deletion of the proposal to harmonise of the legal status of a medicinal product; - the Council has changed the provision on the choice of Committee procedure in relation to decisions to be taken by the Commission following an opinion from the scientific committee. The Council does not consider it consistent with Decision 1999/468/EC to have two different procedures for decisions having the same object and believes that the management procedure is the appropriate procedure to apply for these decisions; - the Council has provided for the possibility of adoption of amendments to the arrangements concerning the periodic safety update reports through a Committee procedure in the light of experience gained; - to improve availability of medicines - particularly in smaller markets - a new article 126a has been introduced that will allow a Member State for public health reasons and under certain circumstances to grant an authorisation for a medicinal product authorised in another Member State; - Article 32 (5) of the Directive allows for the scientific committee to give recommendations for conditions and restrictions in respect of nationally authorised products. The new Article 127a provides for adoption through comitology of decisions requiring Member States to implement such conditions and restrictions in relation to the safe and effective use of centrally authorised products, including vis-à-vis third parties. Other changes include: - adjusting some time limits in relation to the evaluation procedure; - strengthening the supervision powers of the competent authorities by providing them with the explicit right to request the submission of data from the marketing authorisation holder at any time (Article 23); - a new Article 23a has been inserted that requires the marketing authorisation holder to inform the competent authorities of the date of marketing of the medicinal product and any withdrawal from the market of the product; - extending the requirements on good manufacturing practice to certain excipients; - extending the duty of the marketing authorisation holder to report adverse reactions occurring in the territory of a third country; - extending the scope of the provision in Article 111 on inspections. ?

Medicinal products for human use: Community code

The committee adopted the report by Françoise GROSSETÊTE (EPP-ED, F) amending the Council's common position under the 2nd reading of the codecision procedure. It retabled a number of key amendments adopted by Parliament at 1st reading which had not been accepted by Council: - the procedure for granting a marketing authorisation for medicinal products should be completed within 150 days (rather than 210

days as proposed) after a valid application has been submitted, including 80 days for scientific data analysis and preparation of the assessment report; - for the purposes of authorising medicinal products for human use, clinical trials carried out in a developing country should not be recognised, unless the product concerned primarily benefits the population of that country; - as regards data protection for pharmaceutical companies, it should be possible to extend the ten-year protection period up to a maximum of eleven years if, during the first eight of those ten years, the marketing authorisation holder obtains an authorisation for new therapeutic indications bringing "significant clinical benefit" in comparison with existing therapies; - a new article should be inserted on the procedure for the granting of compulsory licences, in the light of the WTO decision of 30 August 2003 on implementing paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health; - after consulting patients', doctors', consumers' and pharmacists' organisations, Member States and other interested parties, the Commission should present a report on current practice with regard to information provision - particularly on the Internet - and its risks and benefits for patients. If appropriate, the Commission should put forward proposals setting out an information strategy to ensure good quality, objective, reliable and non-promotional information on medicinal products and other treatments. The question of the information source's liability should also be addressed; - national authorities should set up a publicly accessible database, independent of pharmaceutical companies, containing updated package leaflets for all pharmaceutical products licensed for sale or dispensing. The database should be structured in such a way as to make a comparison possible of the information available for all medicinal products; - Member States should set up appropriate collection systems for unused or time-expired medicinal products via pharmacies; - activities connected with pharmacovigilance, the functioning of communication networks and market surveillance should receive public funding. ?

Medicinal products for human use: Community code

The European Parliament adopted a resolution drafted by Francoise GROSSETETE EPP-ED, France) making some amendments to the Council's common position. The amendments adopted by Parliament were agreed in advance with the Council for both human and veterinary products: - in order to take account both of the emergence of new therapies and of the growing number of so-called "borderline" products between the medicinal product sector and other sectors, the definition of "medicinal product" should be modified so as to avoid any doubt as to the applicable legislation when a product, whilst fully falling within the definition of a medicinal product, may also fall within the definition of other regulated products; - biological medicinal products similar to a reference medicinal product do not usually meet all the conditions to be considered as a generic medicinal product mainly due to manufacturing process characteristics, raw materials used, molecular characteristics and therapeutic modes of action. When a biological medicinal product does not meet all the conditions to be considered as a generic medicinal product, the results of appropriate tests should be provided in order to fulfil the requirements related to safety (pre-clinical tests) or to efficacy (clinical tests) or to both; - environmental impact must be assessed and, on a case-by-case basis, specific arrangements to limit it must be envisaged. In any event this impact should not constitute a criterion for refusal of a marketing authorisation; - if, during the first eight years of ten years given for marketing protection, the marketing authorisation holder obtains an authorisation for one or more new therapeutic indications which, during the scientific evaluation prior to their authorisation, are held to bring a significant clinical benefit in comparison with existing therapies, the protection can be extended to a maximum of eleven years; - Member States should also take all appropriate measures to ensure that the procedure for granting a marketing authorisation for medicinal products is completed within a maximum of 210 days of the submission of a valid application; - within three years the Commission will, following consultations with patients' and consumers' organisations, doctors' and pharmacists' organisations, Member States and other interested parties, present to the European Parliament and the Council a report on current practice with regard to information provision - particularly on the Internet - and its risks and benefits for patients. Following analysis of the above data, the Commission shall, if appropriate, put forward proposals setting out an information strategy to ensure good-quality, objective, reliable and non-promotional information on medicinal products and other treatments and shall address the question of the information source's liability; - appropriate collection systems must be in place for medicinal products that are unused or have expired; - Member States must ensure that members of staff of the competent authority responsible for issuing authorisations, rapporteurs and experts concerned with the authorisation and surveillance of medicinal products have no financial or other interests in the pharmaceutical industry which could affecttheir impartiality; - the name of the medicinal product must also be expressed in Braille format on the packaging. The marketing authorisation holder should ensure that the package information leaflet is made available on request from patients' organisations in formats appropriate for the blind and partially-sighted. Member States should ensure that appropriate collection systems are in place for medicinal products that are unused or have expired.?

Medicinal products for human use: Community code

The Commission can accept in full the 32 amendments to the Council's common position adopted by Parliament on the proposal for a regulation, the 30 amendments to the Council's common position adopted by Parliament on the proposal for a directive on medicinal products for human use and the 22 amendments to the Council's common position adopted by Parliament on the proposal for a directive on veterinary medicinal products. The Commission notes the convergence of views between the three institutions on the general approach and on the most important issues regarding the compulsory field of application of the centralised procedure, the administrative structure of the agency, the period of data protection, definitions, information for patients and the assessment of the environmental impact. The amendments adopted by Parliament mainly concern the issues of the compulsory field of application of the centralised procedure, the period of data protection and the administrative structure of the agency as far as the regulation is concerned, and the definitions, period of data protection, information for patients and assessment of the environmental impact as regards the two directives on medicinal products for human use and veterinary use.?

Medicinal products for human use: Community code

PURPOSE : to reform Community pharmaceutical legislation. LEGISLATIVE ACT : Directive 2004/27/EC of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use. CONTENT : the Council adopted a package of Community legislation on pharmaceuticals, updating the existing rules with the aim of responding to technical and scientific innovations whilst maintaining a high level of health protection and continuing to ensure the proper functioning of the EU's internal market in the pharmaceuticals sector. The four main objectives of this package are particularly relevant: - to guarantee a high level of public health protection, particularly by providing patients, as swiftly as possible, with innovative and reliable products and by increasing market surveillance by reinforcing monitoring and pharmacovigilance procedures; - to complete the internal market in pharmaceutical products while taking account of the implications of globalisation, and to establish a regulatory and legislative framework that favours the competitiveness of

the European pharmaceuticals sector; - to meet the challenges of the future enlargement of the European Union; - to rationalise and simplify the system, thus improving its overall consistency and visibility, and the transparency of procedures. The new Regulation is aimed at improving the operation of centralised and decentralised authorisation procedures for the placing of medicinal products on the Community market and at amending administrative aspects of the European Medicines Agency. More specifically, the new rules will improve and speed up access to new and innovative pharmaceutical products, building on the proven success of the European Medicines Evaluation Agency (EMEA) set up in 1995. Changes include a new fast-track authorisation procedure, the possibility of conditional authorisation for products and a harmonised period during which test and other data is protected in order to reward innovation. The generic pharmaceutical industry also benefits through clearer rules and procedures and the possibility for them to start testing their products in advance of patent expiry. Finally, the new rules should streamline procedures and reduce red-tape, while at the same time strengthening the supervision of pharmaceutical products. The changes include: the opening of the centralised procedure to more types of new medicines. Currently, the centralised procedure must be used for the authorisation of biotechnology products. Under the new rules the centralised procedure will become mandatory for medicines to treat AIDS, cancer, diabetes, neurodegenerative disorders and orphan diseases and after 4 years this will be further extended to cover medicines for autoimmune diseases and viral diseases. A general review clause will enable further extension to other diseases. In addition, the role of scientific advice in the process is strengthened, as is the EMEA's in relation to scientific matters relating to medicinal products, international activities and its role in providing early scientific advice to companies before they embark on the trials and tests necessary to obtain an authorisation for theirproducts. With a view to increasing and accelerating availability of products, in terms of benefits for patients, the opportunity has been taken to respond to several challenges. The revised legislation aims to increase the availability and speed of access of new and innovative medicines to the European market, while at the same time ensuring that the basic criteria of safety, quality and efficacy are met: - a "fast-track" registration procedure for products of significant therapeutic interest has been introduced allowing these products to be assessed and authorised in an expedited way; - the possibility of a conditional marketing authorisation has been introduced, which allows for a one-year authorisation to be granted provided that there is an important expected health benefit for the patients concerned and that the company agrees to carry out additional monitoring and clinical studies, which will be reviewed at the end of this period; - subject to further additional provisions, a European wide system to make medicinal products available in advance of authorisation for a "compassionate use" will also be possible. This will help to ensure that patients are not discriminated against on the basis, in particular, of the location of the clinical trials performed by a particular company. In addition to the first two provisions, specific measures concerning the availability of veterinary medicinal products are also proposed as well as an incentive scheme to encourage companies to broaden the use of older products for example to cover other species. As regards better access to information for patients, the revised legislation provides for an overall increase in transparency and improves access to the results of the pharmaceutical decision making process, including assessment reports and the summaries of product characteristics. On the issue of promoting the competitiveness of the European pharmaceutical industry in a global context, the revised legislation introduces mechanisms to improve the competitiveness of innovative pharmaceutical, generic and OTC sectors. Concerning data submitted by companies for the approval of medicines, the legislation harmonises the rules governing data protection (data exclusivity). Following transposition of the legislation, whatever the authorisation procedure used, it will not be possible to market generics until ten years have elapsed. This can be extended by a further year if a further innovative indication for the medicine is authorised. This removes current ambiguities of application and allows the innovative pharmaceutical industry more time to recoup its investments before a generic product may be authorised. - for the generic pharmaceutical sector, the new rules introduce the possibility for companies to perform tests to support generic medicine authorisation in Europe and to obtain a marketing authorisation before the end of the data exclusivity period; - in addition, a new definition of generic medicines should provide greater legal security and better application of the regulatory procedures for generic medicines; - for "copies" of biological products, a proper definition of these products, so-called "bio-similar" medicinal product, is introduced. For the Over The Counter (OTC) sector, one year of data exclusivity will be granted on the studies that allowed theswitch of medicinal products from prescription only to OTC; - additionally, the revised legislation introduces the new possibility for an additional period of data protection in case of re-classification of a product as non-prescription ("switch") and in case of a new indication granted to a well-established product. In both cases, the protection will be of one year. The revised legislation includes important changes aiming to optimise, simplify and rationalise the current regulatory processes. The changes reduce the requirement to renew marketing authorisations while reinforcing pharmacovigilance and information sharing provisions. They also include measures to accelerate the Commission's decision making process so that the period between the scientific assessment and marketing a product is shortened. ENTRY INTO FORCE : 30/04/2004. IMPLEMENTATION : 30/10/2005.?